Project Management Office Manager

SPAULDING CLINICAL aims to be the clinical research organization by which all others are measured. Pioneering in our approach to redefining how the industry perceives and achieves success; passionate in our pursuit of ingenious solutions that mitigate risk; loving in our care for our volunteers, customers and employees; and heroic in our ambitions to ensure the health and safety of people around the globe - Spaulding Clinical is taking ***research beyond results*** to create a marketplace of safer drugs.

Original Date: 20 Aug 2019

Revision Date:

Job Summary:

The PMO Manager is responsible for maintaining and growing competency and adherence to project management processes and standards, ensuring consistency with project management practices, and developing and making educated business decisions within the Pharmacology Unit.

The PMO Manager should be proficient in communicating and collaborating with all business units in the company, vendors, team members, Investigators, and Sponsors. The PMO Manager must be able to work both independently but also as a team leader and team member.

Essential Duties and Responsibilities:

- Supervises the daily work, as well as career management, of all Project Managers (PM's) Associate Project Managers (APM's), Clinical Research Trial Associates (CRTA's) and Clinical Administrative Assistants (CAA's) by overseeing adherence to SOP's, Work Instructions, Good Clinical Practice (GCP), FDA regulations, and each individual study protocol.
- Works closely with Project Manager (PM) to ensure all direct reports are being provided accurate and timely feedback during monthly 1:1's.
- Great familiarity with a variety of the industry concepts, practices, and procedures. Relies on extensive experience and judgment to plan and accomplish goals.
- Responsible for clinical trial project cost management and budget review/adherence, as directed by management.
- Always present for customers (Sponsors) by being available for site visits, teleconferences, presentations, and able to provide tours.
- Assists Project Manager in providing training to those new to the Project Management department, understanding the detail and time management skills needed to fulfill the complex responsibilities needed in the APM role.

- Creates project management tools, processes, templates, and checklists and implements them throughout the department with very little oversight.
- Develops and ensures that PMs, APMs, CRTAs, and CAAs are meeting (or exceeding) competency standards and are achieving the needs/goals of the company. Takes action for those who are not.
- Develops proactive efforts that include management of risk, contingencies, and issues.
- Supports Project Manager and project management team in delivering client projects on time, within budget, within scope and are of high-quality.
- Responsible for all project management vendor relationships and ensures appropriate coverage, options for contracting, and quality of vendors (CRA, Medical Monitor, etc.)
- Institutes and delivers weekly metrics as directed and reaches out quarterly to Sponsors for survey results to ensure satisfaction for all projects.
- Implements plan to keep Study Summary spreadsheet up-to-date, at least monthly.
- Develops even greater Leadership skills to increase customer and employee satisfaction.
- Monitors and plans capacity and/or scalability requirements ahead of need. Able to make sound business decisions within scope.
- Directs and participates in the human resource management function for the department by coordinating the selection, promotion, orientation, and performance appraisal process.
- Communicates administrative directives to department personnel.
- Promotes effective intradepartmental relationships.
- Keeps staff updated on important issues and company objectives through scheduled department meetings and assigns action items, while staying united with Clinical Pharmacology management on quarterly/yearly goals.
- Holds 1:1 Meetings with all reports on regular basis for oversight, feedback, and career development purposes and documents clearly and completely.
- Throughout the study, ensures that all study activities are executed per the study protocol, regulatory guidelines, and operational plan.
- Keeps abreast of SOPs, Good Clinical Practice (GCP) and ICH guidelines, state and national laws and ethical standards.
- Participates in quality assurance of clinical research studies and initiates the need for same as it impacts on clinical practice.
- Serves as Project Manager, as needed.

The Statements made in the job description are intended to describe the general nature and level of work being performed by people assigned to this job. These statements are not intended to be an exhaustive list of all responsibilities, duties and skills required of people assigned to this job.

Skills/Qualifications

- Ability to read, write, and interpret the English language.
- Demonstrated ability to be a strong leader inspiring effective teamwork, motivating, mentoring, and encouraging team members to seek solutions.
- Able to hold staff accountable to their duties and responsibilities.
- Knowledge of project management practices

- Demonstrated ability to handle multiple competing priorities and ability to deliver results per deadline
- Excellent planning, organizational, and time management skills
- Able to utilize data and facts to analyze problems and find solutions.
- Excellent oral, written and presentation skills
- Strong written and verbal communication skills, exceptional ability to build and maintain interpersonal relationships with a variety of personalities
- Detail oriented, with ability to produce accurate and timely documents.
- Self-motivated
- Professional in all manners of speaking, with clients and staff, in both casual and formal meetings.
- Must be results oriented, multi-tasking, quick learner, responds to the urgent needs of the team and show a strong track record of meeting deadlines.
- Able to work under pressure within tight timelines
- Strong computer skills (Microsoft Word, Excel, Powerpoint at Intermediate level); inclination to adopt technology to maximize efficiency

Physical Demands:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of the job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Ability to sit, stand, walk, reach with hands and arms, and use hands along with fingers, to handle or feel.
- Ability to lift and/or move up to 25 pounds.
- Specific vision abilities required by this job include clarity of vision both near and far.
- Ability to identify and distinguish colors.

Hazards:

- Potential for exposure to toxic or caustic chemicals
- Potential for exposure to blood borne pathogens

Education and Experience:

- Master's Degree in Business or related field, preferred
- Bachelor's Degree in Nursing, Healthcare Management or related field, required
- Minimum of four years Phase 1 Research Project Management experience, required
- Minimum of two years managerial experience, required
- Possesses the leadership skills to effectively direct employees while in a training environment and ability to properly evaluate comprehension and application of material
- ACRP (or equivalent) certification, preferred

- PMP (or equivalent) certification, preferred
- Knowledge of drug development process and applicable standards, regulations and ICH-GCP for clinical study conduct

Spaulding Clinical Research management has the discretion to hire personnel with a combination of experience and education which may vary from the above listed skills and qualifications.

This is to acknowledge that I have read and understand the above job description. This copy supersedes any others previously distributed. I further understand that Spaulding Clinical may change, add or delete any essential duties and responsibilities described at its discretion with or without prior notice.

Employee Name (Printed) _____ Date _____

Employee Signature _____